Section III (Remarks)

A. Summary of Amendments

By the present amendment, paragraph [0022] of the specification has been amended, to appropriately update the status of U.S. Patent Application No. 09/977,644, which has issued as U.S. Patent No. 6,712,832.

By the present amendment, claims 20, 35, 41, 43, 44, 46, 47, 50, and 52-56 have been amended, claims 33, 34, and 36-40 have been cancelled (with claims 1-19 and 42 having been cancelled previously), and claims 57-73 have been added, such that claims 20-32, 35, 41, and 43-73 are currently pending. No new matter within the meaning of 35 U.S.C. 132 has been introduced by virtue of such amendments.

B. Rejections Under 35 U.S.C. § 112

In the September 8, 2006 Office Action, claims 20-35 and 56 were rejected under 35 U.S.C. 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claimed the subject matter which applicant who regards as the invention. Specifically, claim 20 was rejected as indefinite due to the use of "(s)" in the term "layer(s)," and claim 20 was further rejected as indefinite due to the use of "arranged" in line 7 as requiring clarification of what is arranged for contact with introduced liquid.

In response to such rejections, claim 20 has been amended. The phrase "at least one layer" has been substituted for "layer(s)" preceding the term "thermoplastic polymer film.' Additionally, the phrase "said effervescent material being" has been added before "arranged for contact with introduced liquid" to eliminate any potential ambiguity.

Based on the foregoing amendments to claim 20, withdrawal of the rejections under 35 U.S.C. 112 is respectfully requested.

C. Rejections Under 35 U.S.C. § 103

In the September 8, 2006 Office Action, claims 20-35 and 47-56 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,976,950 to Connors et al. ("Connors"). As noted

previously, claims 33 and 34 have been cancelled, so the rejection of such claims is now moot. As to the remaining claims, the rejections under 35 U.S.C. § 103(a) are traversed in application to such claims as amended herewith for the reasons provided below.

1. Law Regarding Obviousness

Concerning §103 obviousness rejections, three requirements must be met for a *prima facie* case of obviousness. First, **the prior art reference(s) must teach all of the limitations of the claims.** MPEP § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. MPEP § 2143.01. Third, a reasonable expectation of success is required. MPEP § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP § 2143. A further consideration, which applies to all obviousness rejections, is that "[a] prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)." (emphasis in original; MPEP 2141.02).

2. Disclosure of Connors

Connors discloses various methods and apparatuses for attenuating or baffling transient pressure waves in various organs and systems of the body, including cardiovascular, pulmonary, renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous, musculoskeletal, otorhinolaryngical and ophthalmic organs and systems. Connors, col. 1, lines 17-25. Preferred aspects are directed to treatment of disorders of the urinary tract caused by sudden fluctuations of intravesical pressure, to ameliorate symptoms and discomfort associated with incontinence, urgency, frequency, interstitial cystitis, irritable bladder syndrome and neurogenic bladders. Id., lines 26-34.

Connors describes a device having a compressible element that is placed within the human the urinary bladder, in a manner that allows the compressible element to act as a pressure accumulator or attenuator or to attenuate transient pressure events. Id., col. 9, lines 40-43 & col. 10, lines 48-50. An inflatable container includes a flexible wall that contains a compressible

media such as a gas. Id., col. 11, lines 6-31. A flexible wall comprises first and second components bonded together along a seam. Id., col. 11, lines 28-32. Various sealing techniques, such as ultrasonic, radiofrequency, adhesive, or heat sealing, may be used. Id., col. 13, lines 12-15. One example of such a device is illustrated at Figure 5A of Connors, as reproduced below.

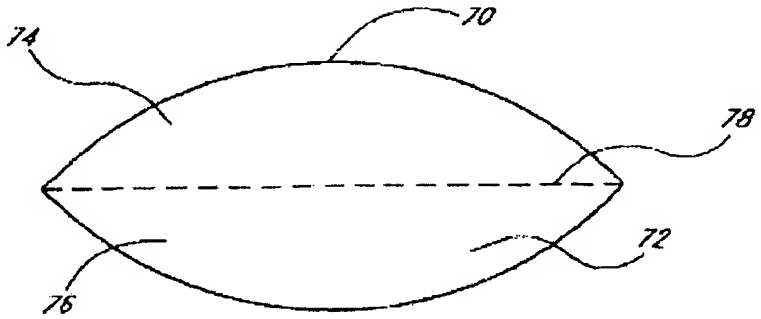


FIG. 5A

Referring to Figure 5A, the first component 74 and second component 76 are bonded together along a seam 78 formed on the outer periphery of the inflatable attenuation device 68. Id., col. 11, lines 28-40. The resulting structure illustrated in Figure 5A resembles a pillow.

Connors refers to various methods of forming multi-layer materials for such attenuation devices, including "extrusion to prepare sheets, plugs, or tubular structures" (e.g., col. 16, line 63 – col. 17, line 7; col. 19, lines 27-29); "injection mold[ing] to fabricate intricately designed parts," (col. 19, lines 29-30); "compression mold[ing] to prepare films" (col. 19, lines 30-31); "dip-molded or extruded" (col. 22, lines 41-43); or "lamination, coextrusion, ... [or] spray molding" (col. 23, lines 62-67).

Connors teaches a variety of device shapes, as indicated by the following passages reproduced below:

> The devices used in embodiments of the present invention may take many shapes. In some instances it may be desirable for manufacturing purposes to have the shape resemble dip-molded devices like condoms, surgical glove fingers, or

> children's toys. However, many other forms may provide better performance, in particular for providing baffling of pressure waves as well as attenuation of pressure spikes. Possible shapes for the attenuation devices include torroid like shapes, similar in form but not size to donuts and inner tubes; spoked wheel forms; horseshoe-like forms; mushroom-like forms; and banana-like forms.

(Col. 22, lines 29-40.)

> FIG. 16A illustrates a toroidal embodiment, in which a plurality of central spokes are provided. FIG. 16B illustrates a crescent or "C" shaped attenuation device. Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section. FIG. 16D illustrates a less arcuate variety as shown in FIG. 16B. In general, the attenuation device 66 may take any of a variety of forms which provides a sufficient volume to achieve the desired attenuation function, and which will minimize or eliminate risk of loss or obstructing outflow through the urethra.

(Col. 24, lines 14-26.)

Connors discloses that attenuation devices may contain various effervescent materials, whether loose or compartmentalized and separated within the device by a "separation wall," "crease," or "peelable bond, fold, or the like" (Connors, col. 32)

3. Patentable Distinctions of Amended Claims Over Connors

Claims 20-32, 35, and 47-56 comprise three independent claims, namely, claims 20, 41, and 55, each of which has been amended herewith. Each of claims 20, 41, and 55 recites, *inter alia*:

> **"a balloon ... formed from two substantially hemispherical vacuum thermoformed half-sections of a multilayer film... wherein the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam ... ."**

(Emphasis added.) Nothing in Connors teaches or remotely suggests the use of **vacuum thermoforming** for producing substantially hemispherical half-sections. To the contrary, Connors mentions a laundry list of other processes (including extrusion, injection molding, compression molding, dip-molding, lamination, coextrusion, and spray molding) but ***fails to mention*** any sort of vacuum thermoforming process.

As illustrated in Figure 3 of the instant patent application, vacuum thermoforming employs a die (whether male or female) including a surface defining various gas withdrawal passages in communication with a vacuum source.

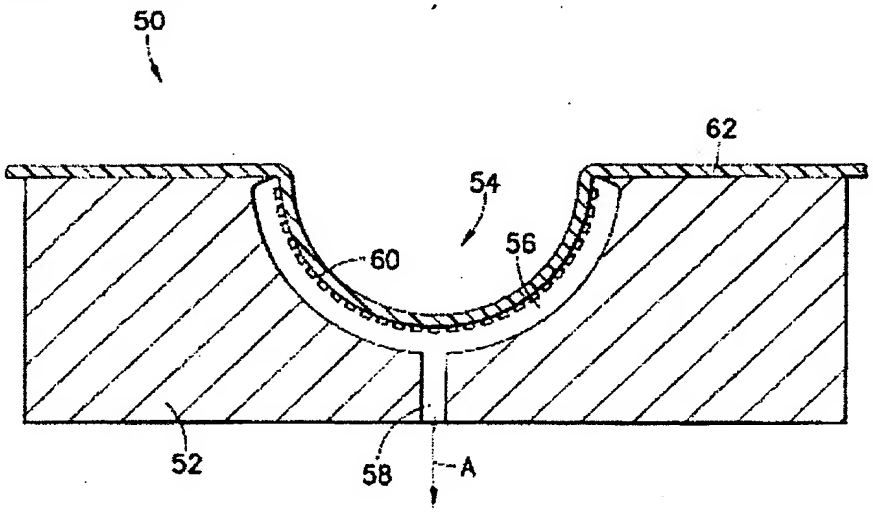


FIG.3

Under negative pressure imposed by the vacuum source, a multilayer film 62 is drawn against the die cavity surface 60, and the evacuated gas is discharged from the die via the discharge passage 58 in the direction indicated by arrow A. Heat is then applied to a laminate film 62 comprising a thermoplastic polymer layer to raise its temperature above the softening temperature of the thermoplastic polymeric material.

Vacuum thermoforming is advantageous to form substantially hemispherical half-sections with materials that are relaxed in such conformation. When two vacuum thermoformed substantially hemispherical half-sections are thereafter bonded along peripheral portions thereof (as illustrated below), the **resulting balloon structure is substantially free of any seam stresses.**

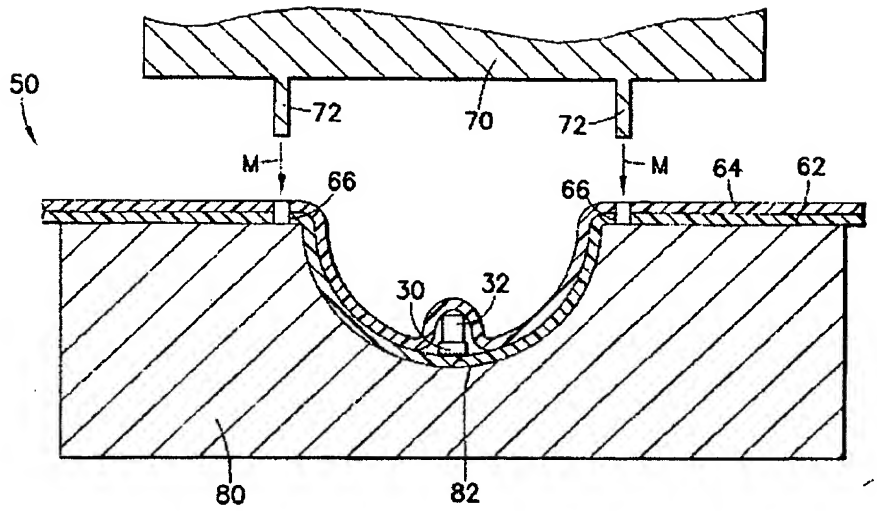


FIG.4

Upon inflation of the balloon produced according to the vacuum thermoforming process employed in the present invention, **undesirable pillowing or pinching along the seam joining the two half-sections is eliminated**. Moreover, the thermoforming process can be completed in advance of the bonding step, such that heating of an effervescent material 32 positionable within the balloon can be avoided.

Connors discloses a variety of manufacturing processes, but unmistakably ***fails* to teach or remotely suggest vacuum thermoforming**, *let alone* as applied to yield hemispherical half-sections of a balloon. Connors is in no way suggestive of such a feature. Accordingly, for at least the reason that Connors fails to teach all of the features of the claims[1] as required by MPEP § 2143.03 to support a *prima facie* case of obviousness, withdrawal of the 35 USC 103(a) rejection of such claims is warranted, and respectfully requested.

New claims 57-73 likewise require "a balloon ... formed from two substantially hemispherical vacuum thermoformed half-sections of a multilayer film... wherein the vacuum thermoformed

[1] E.g., "a balloon ... formed from two substantially hemispherical vacuum thermoformed half-sections of a multilayer film... wherein the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam ... ,

half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam ... ," such that these newly added claims are patentably distinguished over Connors.

Among the various dependent claims, claims 58, 61, 63, and 70 require that "the effervescent material is substantially centrally located along one half-section, with the effervescent material having a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections," as disclosed generally at Figure 4 of the present application. While Connors refers generally to an effervescent material within an attenuation device, whether loose or compartmentalized and separated within the device by a "separation wall," "crease," or "peelable bond, fold, or the like" (Connors, col. 32), Connors fails to teach or suggests the claimed orientation of effervescent material, which orientation is desirable for compactly wrapping the balloon around the material for esophageal insertion into a patient and desirable for low-stress balloon inflation.

D. (No) Fee Payable for Added Claims

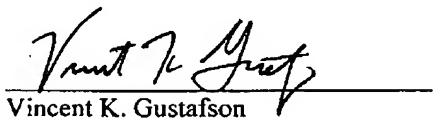
By virtue of the present amendment, four (4) independent claims and forty-six (46) total claims are pending in the application. Claim fees corresponding to five (5) independent claims and fifty-six (56) total claims were previously paid, i.e., with the Preliminary Amendment filed on October 13, 2005 and the Application as filed on April 1, 2004. Accordingly, it is believed that no claim fees are due and payable in connection with the present amendment.

CONCLUSION

Claims 20-32, 35, 41, and 43-73 as provided herein are fully patentably distinguished over the art and in allowable condition. Allowance of the claims therefore is requested and merited.

If any issues remain outstanding, incident to the formal allowance of the application, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue without delay.

Respectfully submitted,



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